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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,886	09/30/2003	Jean-Louis Escary	60711.000023	7856

21967 7590 10/18/2007
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EXAMINER

HISSONG, BRUCE D

ART UNIT	PAPER NUMBER
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1646

MAIL DATE	DELIVERY MODE
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10/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/673,886

Applicant(s)

ESCARY, JEAN-LOUIS

Examiner

Bruce D. Hissong, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 114-193 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 114-177 is/are allowed.
- 6) ☒ Claim(s) 178-193 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/6/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Formal Matters

1. Applicants response to the office action mailed on 2/7/2007, including arguments/remarks and amended claims, was received on 7/6/2007 and has been entered into the record.

2. In the response received on 7/6/2007, the Applicants cancelled claims 1-113 and added new claims 114-193, which are thus currently pending and the subject of this office action.

Information Disclosure Statement

The information disclosure statement received on 7/6/2007 has been considered.

Claim Rejections - 35 USC § 112, first paragraph – enablement and written description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Rejection of claims 85-89 and 97-102 under 35 USC § 112, first paragraph, regarding lack of enablement and lack of adequate written description for polypeptides having less than 100% identity to SEQ ID NO: 2, as set forth on pages 3-6 of the prior office action mailed on 2/7/2007, is moot in response to Applicant's cancellation of the claims. New claims 114-193 are drawn to polypeptides having 95% or greater homology to the polypeptide of SEQ ID NO: 2, with the functional limitations that said polypeptides exhibit at least one antiviral, antiproliferative, or immunomodulatory activity. Therefore, the enablement and written description rejections as originally applied to claims 85-89 and 97-102 will not be applied to claims 114-193.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Rejection of claims 85-89 and 100-102 under 35 USC § 112, second paragraph, as being definite regarding the metes and bounds of the term “equivalent position”, as set forth on pages 6-7 of the prior office action mailed on 2/7/2007, is moot in response to Applicant’s cancellation of claims 85-89 and 100-102, and the submission of new claims 14-193 which do not recite the limitation “equivalent position.”

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Rejection of claims 85-89 and 97-100 under 35 USC § 102(b) as being anticipated by Goeddel *et al* (GB 2 079 291), as set forth on pages 7-8 of the office action mailed on 2/7/2007, is moot in response to Applicants cancellation of the claims. Furthermore, in the response received on 7/6/2007, the Applicants argue that Goeddel *et al* does not teach a polypeptide with at least 95% identity to the polypeptide of SEQ ID NO: 2 and one of the following SNPs: K179E, Q102K, Q114H, V127D, A42G, as recited in currently pending claims 114-193.

This argument has been fully considered and is found persuasive. Therefore, this rejection will not be applied to new claims 114-193.

2. Rejection of claims 85-89 and 97-100 under 35 USC § 102(e) as being anticipated by Chen *et al* (US 6,299,877), as set forth on page 8 of the office action mailed on 2/7/2007, is moot in response to Applicants cancellation of the claims. Furthermore, in the response received on 7/6/2007, the Applicants argue that Chen *et al* does not teach a polypeptide with at least 95% identity to the polypeptide of SEQ ID NO: 2 and one of the following SNPs: K179E, Q102K, Q114H, V127D, A42G, as recited in currently pending claims 114-193.

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This argument has been fully considered and is found persuasive. Therefore, this rejection will not be applied to new claims 114-193.

3. Rejection of claims 85-89 and 97-100 under 35 USC § 102(e) as being anticipated by Goeddel *et al* (US 6,482,613), as set forth on page 8 of the office action mailed on 2/7/2007, is moot in response to Applicants cancellation of the claims. Furthermore, in the response received on 7/6/2007, the Applicants argue that Goeddel *et al* ('613) does not teach a polypeptide with at least 95% identity to the polypeptide of SEQ ID NO: 2 and one of the following SNPs: K179E, Q102K, Q114H, V127D, A42G, as recited in currently pending claims 114-193.

This argument has been fully considered and is found persuasive. Therefore, this rejection will not be applied to new claims 114-193.

Search of additional SNP species

The requirement for restriction mailed on 7/5/2006 required an election of species among different recited SNPs (K179E, Q102K, Q114H, V127D, and A42G). The Applicants elected the K179E species, which was the subject of the office action mailed on 2/7/2007. New claims 114-129, which read on the K179E SNP, are free of the art and otherwise in condition for allowance. Accordingly, claims 130-193, drawn to other SNP species, have now been searched. Claims 130-177, drawn to the Q102K, Q114H, and V127D SNPs, are also free of the art and are otherwise in condition for allowance. Claims 178-193, drawn to the A42G SNP, are rejected as set forth below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 178-193 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ullrich *et al* (J. Mol. Biol., 1982, Vol. 156, pages 467-486 – cited in the information disclosure statement received on 1/13/2004).

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The claims of the instant invention are drawn to an isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 2, or amino acids 24-189 of SEQ ID NO: 2 wherein said polypeptide comprises an A42G SNP. The claims also recite polypeptides having 95%, 97% and 99% identity to SEQ ID NO: 2 wherein said polypeptides exhibit at least one antiviral, antiproliferative, or immunomodulatory activity, and compositions of said polypeptides.

Ullrich teaches IFN- α polypeptide, and specifically "leukocyte interferon-C, L, J, F, and H" polypeptides. Leukocyte interferon-F corresponds to IFN- α 21, which also is the polypeptide of SEQ ID NO: 2 of the instant invention. Although Ullrich does not specifically recite an IFN- α 21/SEQ ID NO: 2 polypeptide with an A42G SNP, Ullrich does present an alignment of different IFN- α polypeptide sequences (Fig. 11). In this alignment, all shown IFN- α polypeptide sequences have either an alanine (A) or a glycine (G) at position 42. Therefore, a person of ordinary skill in the art, at the time the instant invention was conceived, would have been motivated to substitute the alanine at position 42 of SEQ ID NO: 2 with a glycine. The motivation to do so comes from the disclosure of Ullrich, showing that either a glycine or an alanine at position 42 of IFN- α polypeptides results in a functional IFN- α with biological activity, and thus a skilled artisan would know that the alanine of SEQ ID NO: 2 could be substituted with a glycine to create a functional IFN- α polypeptide. Furthermore, although Ullrich does not specifically recite polypeptides with 95%, 97%, or 99% identity to SEQ ID NO: 2, the alignment of Fig 11 shows other amino acid positions of IFN- α 21/SEQ ID NO: 2 that differ from other IFN- α sequences, and shows the corresponding amino acids of the other sequences. Thus, Ullrich teaches other potential substitutions to SEQ ID NO: 2 which could be made, resulting in polypeptides with 95%, 97%, or 99% identity to SEQ ID NO: 2. Finally, although Ullrich does not specifically teach pharmaceutical compositions of any specific polypeptide, one of ordinary skill in the art would know that IFN- α polypeptides are useful therapeutically and would thus be motivated to create pharmaceutical compositions comprising a polypeptide of SEQ ID NO: 2 comprising an A42G SNP, or other polypeptides having 95% or greater homology to SEQ ID NO: 2, wherein said compositions also comprise useful pharmaceutical excipients and additives.

Conclusion

Claims 114-177 are allowable.

Claims 178-193 are not allowable.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hisson, Ph.D., whose telephone number is (571) 272-3324. The examiner can normally be reached M-F from 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D., can be reached at (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bruce D. Hisson
Art Unit 1646

/Robert S. Landsman/
Primary Examiner, Art Unit 1647